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EXAMINER				
COONEY, JOHN M				
ART UNIT		PAPER NUMBER		
1796				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary

Application No.

10/749,742

Applicant(s)

DATTA ET AL.

Examiner

John Cooney

Art Unit

1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 50, 52-55 and 115-122 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 50, 52-55 and 115-122 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Applicant's arguments filed 2-13-09 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13, 50, 52-55, and 115-122 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants originally filed supporting disclosure does not provide support for the range of polymers now defined by the component (v.) of their claims. Though applicants' originally filed supporting disclosure identifies polymers falling within the group of polymers now defined by component (v.) of their claims, such as components (i.)-(iv.), it is not seen to be supportive of other polymers, beyond the groups of polymers identified by the supporting disclosure, that are formed by the reaction of isocyanate and polyols as defined by component (v.). This is a new matter rejection.

Claims 1-13, 50, 52-55, and 115-122 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants originally filed supporting disclosure does not provide support for elastomeric matrixes that are "substantially free of allophanate, biuret, and isocyanurate linkages" such that it is evident that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

It has long been held that the express exclusion of certain elements implies the permissible inclusion of all other elements not so expressly excluded which clearly demonstrates that the introduction of negative limitations not explicitly provided for by the specification as originally filed do, in fact, introduce new concepts and is therefore new matter. *Ex parte Grasselli* 231 USPQ 394.

Support for this claim language is not seen at page 20 lines 28-29 or any other portion of applicants' supporting disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "biodurable" in claims 2 and 4 is a relative term which renders the claim indefinite. The term "biodurable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It can not be determined what degree of bio-resiliency is intended to be encompassed by the claimed term "biodurable".

Applicants' arguments have been considered. However, rejection is maintained. Though the supporting disclosure offers general, descriptive information pertaining to the term "biodurable", it does not offer specific language which allows an ordinary practitioner to ascertain what degree of breakdown, degradation and/or deterioration resistance is required to meet the condition of being "biodurable". The recitation of a time frame for which the product is "biodurable" is of no remedy to the above mentioned problem because it does not address the confusion in determining what degree of breakdown, degradation and/or deterioration resistance is required to meet the condition of being "biodurable".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13, 50, 52-55, 115-119 and 122 are rejected under 35 U.S.C. 102(b) as being anticipated by Brady et al. {2002/0072550}.

Brady et al. discloses preparations of reticulated/porous, biostable, polyether or polycarbonate based polyurethane elastomeric materials based on isocyanates as claimed reading on the preparations of applicants' claims (see abstract, drawings, paragraphs [0005]-[115], and examples, as well as, the entire document). Though Brady et al. does not specify the ranges of recovery and compressibility values of applicants' claims, it does provide for composition that are not seen to differ in make-up from the compositions claimed, and it provides that its formed articles have good integrity such that it is held that these features are inherent to the products having high compressibility and high recoverability disclosed by Brady et al. Based on the drawings, the void content, and overall make-up of the compositions of Brady et al., it is held that the pore diameters of applicants' claims are inherent to the teachings of Brady et al.

As to features of new claims 115-122 not already addressed above, it is not seen that distinction is evident. Brady et al. discloses products of dimensions suitable for

implantation, mixtures of 2,4- and 4,4- MDI {see paragraphs [0070]—[0071]}, polyols reading on hydrocarbon polyols{see paragraphs [0070]—[0071]}.

It is not seen that applicants' claims distinguish over Brady et al. based on the content of 2,4-MDI because Brady et al. in less preferred embodiments of their disclosure {paragraphs [0033] & [0034]} identifies that crude MDI's may be employed. It is held that contents of 2,4-MDI as claimed are inherently possessed by these crude mixtures, and, as to the negative teaching of Brady et al., it has long been held that the disclosure of a composition of matter in a reference may be anticipatory even though the reference indicates that the composition is not preferred or even that it is unsatisfactory for the intended purpose. In re Nehrenberg 126 USPQ 383.

Applicants' arguments have been considered. However, rejection is maintained.

It is not seen that applicants' claims distinguish over the teaching of Brady et al. based on the substantial exclusion language of the claims. Given that applicants' claims allow for excesses of isocyanate indicates an allowance for the formation of isocyanurate linkages. It is seen that Brady et al.'s fully considered teaching, which allows for mere excesses of isocyanate to isocyanate reactive material reads on and/or inherently discloses substantial exclusion of isocyanurate to the degree required by applicants' claims.

Further, as to the ranges of index values of applicants' claims, it is not seen that Brady et al. is limited solely to the preferred teachings of its disclosure. Brady et al. in paragraph [0035] specifically identifies an embodiment of their invention wherein

isocyanate is in excess. That preferred, specific degrees of excess beyond the index values of applicants' claims are identified by Brady et al. does not negate that Brady et al.'s anticipatory teaching reads on Index values of just greater than 1.0 and beyond.

As to applicants' arguments as to the manner of reticulating their product, it is held that difference in the product as claimed has not been demonstrated to be evident based on the manner in which the product has been reticulated. It has long been held that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim it is appropriate for the examiner to make a rejection under both the applicable section of 35 USC 102 and 35 USC 103 such that burden is placed upon applicant to provide clear and convincing factual evidence that the respective products do in fact differ in kind – In re Brown, 59 CCPA 1063, 173 USPQ 685 (1972); In re Fessman, 180 USPQ 324 (CCPA) – and to come forward with evidence establishing unobvious differences between the claimed product and the prior art product. In re Marosi 218 USPQ 290. That certain reticulation methods require different or don't require any debris removal operations is not seen to be evidence of difference between the reticulated product of applicants' claims and those of Brady et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 120-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brady et al. {2002/0072550} as applied to claims 1-13, 50, 52-55, 115-119 and 122 above, and further in view of WO-01/74582(WO-'582).

Brady et al. differs from the claims in that it does not disclose employment of aliphatic isocyanates in the making of its polyurethanes. However, WO-'582 (see page 12, as well as, the entire document) discloses aliphatic isocyanates to be acceptable reactants in making reticulated polyurethane materials to be useful for the purpose of providing good urethane products used in biological applications. Accordingly, it would have been obvious for one having ordinary skill in the art to have employed the aliphatic isocyanates of WO-'582 in making the products of Brady et al. for the purpose of producing acceptable biological articles in order to arrive at the products of applicants' claims with the expectation of success in the absence of a showing of new or unexpected results.

The following is set forth in the alternative to the rejection of claim 119 under 102(b) over Brady et al.:

Claims 119 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brady et al. {2002/0072550} as applied to claims 1-13, 50, 52-55, 115-118 and 122 above.

Brady et al. differs from the claims in that it does not disclose employment of amounts of 2,4-MDI as required by applicants' claims. However, Brady et al. does provide for the less preferred alternative employment of crude MDI in the making of

products of their disclosure and the preferred use of lower 2,4-MDI contents for the preferred purposes of their invention. Accordingly, it would have been obvious for one having ordinary skill in the art to have employed less preferred, less pure mixtures of 4,4-MDI containing greater contents of 2,4-MDI within the practice of the teachings of Brady et al. in making the products of Brady et al. for the purpose of producing acceptable biostable articles at reduced prices in order to arrive at the products of applicants' claims with the expectation of success in the absence of a showing of new or unexpected results. Further, all disclosures of the prior art, including unpreferred or auxiliary embodiments, must be considered in determining obviousness. *In re Mills*, 176 USPQ; *In re Lamberti*, 192 USPQ 278; *In re Boe*, 148 USPQ 507.

As to the closeness of the endpoints of the ranges of values, it has long been held that where the general conditions of the claims are disclosed in the prior art, discovering the optimal or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233; *In re Reese* 129 USPQ 402 . Further, a prima facie case of obviousness has been held to exist where the proportions of a reference are close enough to those of the claims to lead to an expectation of the same properties. *Titanium Metals v Banner* 227 USPQ 773. **(see also MPEP 2144.05 I)** Similarly, it has been held that discovering the optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272,205 USPQ 215 (CCPA 1980).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13, 50, 52-55 and 115-122 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-101 of copending Application No. 11/652,763. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are directed towards preparations which overlap in structure and make-up with the instant claims such that operation within the controls of its disclosure for the purpose of providing acceptable implantable articles would have been obvious to one having ordinary skill in the absence of a showing of new or unexpected results attributable to differences in the claims. At least claim 1 of the instant claims is fully encompassing of claim 1 of the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-13, 50, 52-55 and 115-122 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 8-22, 41-46, and 89-141 of copending Application No. 10/848,624. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are directed towards preparations which overlap in structure and make-up with the instant claims such that operation within the controls of its disclosure for the purpose of providing acceptable implantable articles would have been obvious to one having ordinary skill in the absence of a showing of new or unexpected results attributable to differences in the claims. At least claim 1 of the instant claims is fully encompassing of claim 1 of the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Cooney whose telephone number is 571-272-1070. The examiner can normally be reached on M-F from 9 to 6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck, can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/John Cooney/

Primary Examiner, Art Unit 1796